HOUSE BILL 1190
By Shepard

SENATE BILL 1197

By McNally

AN ACT to amend Tennessee Code Annotated, Title 63, relative to pharmacy in order to enact the "Safe Prescription Drug Act of 2007."

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF TENNESSEE:

SECTION 1. Tennessee Code Annotated, Section 63-10-204, is amended by deleting subdivision (19) and by substituting instead the following as a new subdivision (19):

(19) "Manufacturer" means a person licensed or approved by the FDA to engage in the manufacture of drugs or devices;

SECTION 2. Tennessee Code Annotated, Section 63-10-204, is amended by adding the following as new subdivisions to be appropriately designated:

( ) "Authorized distributor of record" means a wholesale distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's prescription drug. An ongoing relationship is deemed to exist between such wholesale distributor and a manufacturer when the wholesale distributor, including any affiliated group of the wholesale distributor, as defined in Section 1504 of the Internal Revenue Code, complies with any one of the following:

(1) The wholesale distributor has a written agreement currently in effect with the manufacturer evidencing such ongoing relationship; and

(2) The wholesale distributor is listed on the manufacturer's current list of authorized distributors of record, which is updated by the manufacturer on no less than a monthly basis;

( ) "Chain pharmacy warehouse" means a permanent physical location for drugs or devices that acts as a central warehouse and performs intracompany sales and transfers of prescription drugs or devices to chain pharmacies, which are members of

the same affiliated group, under common ownership and control. Chain pharmacy warehouses must be licensed as wholesale distributors;

( ) "Co-licensee" means a pharmaceutical manufacturer that has entered into an agreement with another pharmaceutical manufacturer to engage in a business activity or occupation related to the manufacture or distribution of a prescription drug and the national drug code on the drug product label shall be used to determine the identity of the drug manufacturer;

( ) "Drop shipment" means the sale, by a manufacturer, that manufacturer's co-licensee, that manufacturer's third party logistics provider, or that manufacturer's exclusive distributor, of the manufacturer's prescription drug, to a wholesale distributor whereby the wholesale distributor takes title but not possession of such prescription drug and the wholesale distributor invoices the pharmacy, the chain pharmacy warehouse, or other designated person authorized by law to dispense or administer such prescription drug, and the pharmacy, the chain pharmacy warehouse, or other designated person authorized by law to dispense or administer such prescription drug receives delivery of the prescription drug directly from the manufacturer, that manufacturer's co-licensee, that manufacturer's third party logistics provider, or that manufacturer's exclusive distributor, of such prescription drug. Drop shipments shall be part of the "normal distribution channel";

( ) "Exclusive distributor" means an entity that:

(A) Contracts with a manufacturer to provide or coordinate warehousing, wholesale distribution, or other services on behalf of a manufacturer and who takes title to that manufacturer's prescription drug, but who does not have general responsibility to direct the sale or disposition of the manufacturer's prescription drug;

(B) Is licensed as a wholesale distributor under this chapter; and

(C) To be considered part of the normal distribution channel, must also be an authorized distributor of record;

( ) "Normal distribution channel" means a chain of custody for a prescription drug that goes from a manufacturer of the prescription drug, the manufacturer's co-licensee, the manufacturer's third-party logistics provider, or the manufacturer's exclusive distributor to:

(A) An authorized distributor of record, to a pharmacy to a patient or other designated persons authorized by law to dispense or administer such prescription drug to a patient;

(B) An authorized distributor of record, to a chain pharmacy warehouse to that chain pharmacy warehouse's intracompany pharmacy to a patient or other designated persons authorized by law to dispense or administer such prescription drug to a patient;

(C) A chain pharmacy warehouse to that chain pharmacy warehouse's intracompany pharmacy to a patient or other designated persons authorized by law to dispense or administer such prescription drug to a patient;

(D) A pharmacy to a patient;

(E) Other designated persons authorized by law to dispense or administer such prescription drug to a patient; or

(F) Another entity as prescribed by the board's regulations;

() "Pedigree" means a statement or record in a written form or electronic form, approved by the board, that records each wholesale distribution of any given prescription drug, excluding veterinary prescription drugs, which leaves the normal distribution

channel. The pedigree shall minimally include the following information for each transaction:

(A) The source of the prescription drug, including the name and principal address of the seller;

(B) The proprietary and established name of the prescription drug, the amount of the prescription drug, the national drug code number, its dosage form and dosage strength, the date of the purchase, the sales invoice number, container size, number of containers, expiration date, and lot number or control number of the prescription drug;

(C) The business name and address of each owner of the prescription drug and its shipping information, including the name and address of the facility of each person certifying delivery or receipt of the prescription drug;

(D) Information that states that the wholesale distributor has conducted due diligence of the wholesale distributor from which the wholesale distributor purchased;

(E) A certification from the designated representative of the wholesale distributor that the information contained therein is true and accurate under penalty of perjury; and

(F) Other items as prescribed by the board's regulations;

( ) "Third party logistics provider" means an entity that:

(A) Provides or coordinates warehousing, distribution, or other services on behalf of a manufacturer, but does not take title to the prescription drug or have general responsibility to direct the prescription drug's sale or disposition;

(B) Is licensed as a wholesale distributor under this chapter; and

(C) To be considered part of the normal distribution channel must also be an authorized distributor of record;

( ) "Wholesale distribution" means the distribution of prescription drugs or devices by wholesale distributors to persons other than consumers or patients, and includes the transfer of prescription drugs by a pharmacy to another pharmacy if the units value of the goods transferred exceeds five percent (5%) of total prescription drug units sold by either the transferor or transferee pharmacy during any consecutive twelve-month period. Wholesale distribution does not include:

(A) The sale, purchase, or trade of a prescription drug or device, an offer to sell, purchase, or trade a prescription drug or device, or the dispensing of a prescription drug or device pursuant to a prescription;

(B) The sale, purchase, or trade of a prescription drug or device or an offer to sell, purchase, or trade a prescription drug or device for emergency medical reasons;

(C) Intracompany transactions, unless in violation of own use provisions;

(D) The sale, purchase, or trade of a prescription drug or device or an offer to sell, purchase, or trade a prescription drug or device among hospitals, chain pharmacy warehouses, pharmacies, or other health care entities that are under common control;

(E) The sale, purchase, or trade of a prescription drug or device or the offer to sell, purchase, or trade a prescription drug or device by a charitable organization described in 501(c)(3) of the Internal Revenue Code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(F) The purchase or other acquisition by a hospital or other similar health care entity that is a member of a group purchasing organization of a prescription

drug or device for its own use from the group purchasing organization or from other hospitals or similar health care entities that are members of these organizations;

(G) The transfer of prescription drugs or devices between pharmacies pursuant to a centralized prescription processing agreement;

(H) The sale, purchase, or trade of blood and blood components intended for transfusion;

(I) The return of recalled, expired, damaged, or otherwise non-salable prescription drugs, when conducted by a hospital, health care entity, health care clinic, physician's offices, pharmacy, or charitable institution in accordance with the board's regulations; or

(J) The sale, transfer, merger, or consolidation of all or part of the business of a retail pharmacy or pharmacies from or with another retail pharmacy or pharmacies, whether accomplished as a purchase and sale of stock or business assets, in accordance with the board's regulations.

(K) The distribution of drug samples by manufacturers' and authorized distributors' representatives;

(L) The sale of minimal quantities of drugs by retail pharmacies to licensed practitioners for office use;

(M) Distribution of drugs that are earmarked by state, federal or local government for use in emergencies or disasters;

(N) Distribution of drugs to under title 63, chapter 10, part 5; or

(O) The distribution of drugs by a repackager that is licensed with the FDA as a repackager;

( ) "Wholesale distributor" means any person engaged in wholesale distribution of prescription drugs or devices in or into the state, including but not limited to manufacturers, repackagers, own-label distributors, private-label distributors, jobbers, brokers, warehouses, including manufacturers' and distributors' warehouses, co-licensees, exclusive distributors, third party logistics providers, chain pharmacy warehouses and wholesale drug warehouses, independent wholesale drug traders, and retail pharmacies that conduct wholesale distributions.

SECTION 3. Tennessee Code Annotated, Title 63, Chapter 10, Part 2, is amended by adding the following as a new section:

63-10-___.

(a)

(1) Effective January 1, 2008, wholesale distributors shall be required to maintain a pedigree for each prescription drug that is wholesale distributed outside the normal distribution channel, in accordance with policy and procedure set by the board. This subdivision (a)(1) will expire when subdivision (a)(2) becomes operative. Entities within the normal distribution channel shall provide information necessary to generate a pedigree, about the distribution history of the product, if requested by a pharmacy.

(2) Effective at a date set by the board, pedigrees shall be maintained for each wholesale distribution of a prescription drug starting with the sale by a manufacturer through acquisition and sale by any wholesale distributor, until final sale to a pharmacy or other authorized person administering or dispensing the prescription drug. Pedigrees may be implemented through an approved and readily available system that electronically tracks and traces the prescription drug. This electronic tracking system will be deemed to be readily available only

upon there being available a standardized system originating at the manufacturer and capable of being used on a wide scale across the entire healthcare industry which includes manufacturers, wholesale distributors, and pharmacies. Consideration must be given, however, to the large-scale implementation of this technology across the supply chain and the technology must be proven to have no negative impact on the safety and efficacy of the pharmaceutical product. Nevertheless, implementation should not be unnecessarily delayed.

(b)

(1) Each wholesale distributor that provides services in this state, whether the wholesale distributor is located within this state or outside of this state, shall be licensed by the board and shall renew the license using an application provided by the board.

(2) The board shall promulgate rules to establish standards and requirements for the issuance and maintenance of a wholesale distributor license.

(3) The board shall have the authority to recognize a third party to inspect and accredit wholesale distributors.

(4) The board may license by reciprocity, a wholesale distributor that is licensed under the laws of another state, if:

(A) The requirements of that state are deemed by the board to be substantially equivalent; or

(B) The applicant is accredited by a third party recognized by the board.

(5) Each facility that engages in wholesale distribution must undergo an inspection by the board or a third party recognized by the board for the purpose

of inspecting the wholesale distribution operations prior to initial licensure and periodically thereafter in accordance with a schedule to be determined by the board but not less than once every three (3) years.

(c) Manufacturers engaged in wholesale distribution need only satisfy the minimum federal requirements for licensure provided in FDA regulations 21 CFR Part 205 to provide wholesale distribution services.

(d)

(1) If a person engages in the wholesale distribution of prescription drugs in violation of this section, the person has committed a Class C felony.

(2) If a person knowingly engages in wholesale distribution of prescription drugs in violation of this section, the person has committed a Class A felony, and in addition to imprisonment may be fined not more than fifty thousand dollars ($50,000).

SECTION 4. This act shall take effect July 1, 2007, the public welfare requiring it.